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| 10/530,790 | 04/08/2005 | Hideko Kosaka | 10873.1670USWO | 9379 |
| 52835 7590 07/16/2008 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902 | | | | |
| EXAMINER | | | | |
| WHITE, DENNIS MICHAEL | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1797 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,790

Applicant(s)

KOSAKA, HIDEKO

Examiner

DENNIS M. WHITE

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/2/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. Amendment filed on 6/2/2008 is noted. Claims 1 and 12 are amended, claims 17-18 are new, and claim 9 is cancelled. Currently claims 1-8 and 10-18 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-8, 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al (USP 4,275,031) in view of Puglia (USP 5,374,561).

Regarding claims 1-4, 6, 10-11, and 17, Fischer et al teach a test kit (piece) (col. 6 lines 19-24) used in medical laboratory diagnostic tests (col. 1 lines 11-13) comprising: Chromazurol S (reads on formulas 1-4) or Eriochrome cyanine (reads on formula 6) (col. 4 lines 29 and 33). The test kit is fully capable of being used on creatinine measurements. Fischer et al is silent about the compound further comprising a metal or its salt that forms a colored complex with the compound, wherein the metal is a transition metal from a group consisting of Cu (II) and Pd (II). Puglia teaches a creatinine assay using soluble cupric salt (reads on "metal or its salt", "transition metal", and "Cu (II)"), hydroperoxide and an oxidizable indicator (Puglia: Abstract). It is desirable to include a cupric salt in a creatinine assay because it allows the measurements to be done at neutral pH, instead at high pH, thus avoiding the carriers, such as filter paper, from becoming brittle and overcoming the difficulty of obtaining even distribution of the alkali throughout the carrier matrix (col. 1 line 62-col. 2 line 6).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a soluble cupric salt with the test kit of Fischer et al in the measurement

of creatinine to form a colored complex with the indicator as motivated by Puglia to obtain the above advantage.

Regarding claims 5 and 7, Fischer/Pugia teach the compounds Chromazurol S (reads on formulas 1-4), Eriochrome cyanine (reads on formula 6), or pyrocatechol-3,5-disulphonic acid (col. 4 line 66) for diagnostic testing, but are silent about of Chromazurol B of claim 5 and pyrocatechol violet of claim 7. Structural similarities have been found to support a prima facie case of obviousness. See, e.g., In re May, 574 F.2d 1082, 1093-95, 197 USPQ 601, 610-11 (CCPA 1978) (stereoisomers); In re Wilder, 563 F.2d 457, 460, 195 USPQ 426, 429 (CCPA 1977) (adjacent homologs and structural isomers); In re Hoch, 428 F.2d 1341, 1344, 166 USPQ 406, 409 (CCPA 1970) (acid and ethyl ester); In re Druey, 319 F.2d 237, 240, 138 USPQ 39, 41 (CCPA 1963) (omission of methyl group from pyrazole ring). Generally, some teaching of a structural similarity will be necessary to suggest selection of the claimed species or subgenus. See also In re Hoeksema, 399 F.2d 269, 158 USPQ 596 (CCPA 1968) (A claim to a compound was rejected over a patent to De Boer which disclosed compounds similar in structure to those claimed (obvious homologs) and a process of making these compounds).

Therefore, it would have been obvious to one of ordinary skill to substitute chromazurol B or pyrocatechol violet as known equivalents of chromazurol S, Eriochrome cyanine, or pyrocatechol-3,5-disulphonic acid to obtain the expected result of indicators capable of color changes.

Regarding claim 8, Fischer/Pugia teach a second film over the reagent zone in such a way that a hollow space is open on two sides ("compound is included in a porous material") (col. 6 lines 34-39).

Regarding claim 12, Fischer/Pugia teach the compound A and the metal or its salt, but are silent about a molar ratio of 30:1 to 1:15 of compound A to metal or its salt. This ratio is result effective because the adding of a metal or its salt to the compound A is done in order to make a colored complex at a neutral pH. Adding too little metal will give no color change and adding too much metal will provide excess metal that will interfere with the reaction with creatinine. Therefore, it would have been obvious to one of ordinary skill to optimize the ratio of metal or its salt to the compound A in Fischer/Pugia in order to obtain a proper color change of the complex of compound A and the metal or its salt.

Regarding claim 13, Fischer/Pugia teach the use of a succinic acid buffer (buffer agent) (col. 4 lines 34-35).

Regarding claim 14, Fischer/Pugia teach the buffer to maintain the pH at 7.0, but are silent about the ratio of the indicator ("compound") to buffer agent being 1:10 to 1:1000. It would have been obvious to one of ordinary skill at the time of the invention to optimize the ratio of the indicator to the buffer in order to obtain the expected result of maintaining the desired pH.

Regarding claims 15-16, Fischer/Pugia teach the use of the organic polymers, such as polyvinylpyrrolidone (PVP) and polyvinyl alcohols (PVA) (col. 3 lines 37-44) with a ratio of reagent (compound) to polymer that can vary between 10:1 and 0.1:1 (reads

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on "ratio (molar ratio A:D) of 50:1 to 3:1" (col. 6 lines 12-15). PVP and PVA of Fischer are identical to those compounds indicated as nonionic surfactants in the Applicant's specification (Page 7 lines 21-25).

Regarding claim 18, Fischer/Pugia teach the metal is copper and other transition metals such as Co(II) forming complexes with creatinine (col. 2 line 15-21) ("metal selected from a group consisting of Pd(II), U(VI), Zr(IV), Ti(IV), Mn(II), Fe(III), Co(II), Ni(II), Mo(VI), and Sn(IV)").

Response to Arguments

4. Applicant's arguments filed 6.02.2008 have been fully considered but they are not persuasive.
5. Applicants argue that the combination of Fischer and Pugia is improper because of the detection of color is taught in each reference as a result of the creatinine measurement and the Applicants invention is directed to the absence of color detection. Applicants argue that this fact causes the references to lead away from evaluating creatinine by the disappearance as opposed to the production of color. In response, the Office notes that all the claimed features are taught in combination of Fischer and Pugia and the motivation of record is sufficient for the combination to be obvious. The intended use and method limitations of detecting color disappearance are not within the scope of the claims. Furthermore, Fischer and Pugia detect a change in color which does not exclude detecting the disappearance of color.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DENNIS M. WHITE** whose telephone number is (571)270-3747. The examiner can normally be reached on **Monday-Thursday, EST 8:00-5:00**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

dmw